

**REMARKS**

Reconsideration of the above-identified application in view of the following remarks is respectfully requested.

Claims 1-207 are pending in this case. Claims 43-109 and 148-207 have been withdrawn from further consideration as being drawn to a non-elected invention. Claims 24 and 136 have been currently withdrawn from further consideration as being drawn to a non-elected species. Claims 1-23, 25-42, 110-135 and 137-147 have been examined on merits. Claims 1-23, 25-42, 110-135 and 137-147 have been rejected. Claims 17, 33, 38, 129 and 145 have now been canceled. Claims 1, 22, 32, 41, 110, 134 and 146 have now been amended.

***Specification***

In one particular, the Examiner has stated that the incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication, is improper and has further stated that the Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office.

Applicant contends that no unpublished references have been cited in the specification. The only references cited in the specification of the instant application which might have been the subject of questionable publication are the provisional applications from which the instant application claims priority and which are cited on the first paragraph of page 1 of the application. However, as can be seen in the public PAIR web page of the Office, these provisional applications have been published on the USPTO's website.

In another particular, the Examiner has stated that the lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors.

Applicant has thoroughly reviewed the application and has found two typographical errors on page 27, lines 18 (paragraph [0146]) and 22 (paragraph [0147], where the word "acidified" was misspelled. Appropriate correction has been made.

In another particular, the Examiner has stated that the trademarks LUXIQ® and OLUX® should be capitalized throughout the application.

Page 3, line 32 (paragraph [0017]), and page 27, lines 5 (paragraph [0144]) and 18 (paragraph [0149]) have been amended accordingly.

Applicant believes to have overcome the Examiner's objections to the specification.

### ***35 U.S.C. §112 First Paragraph Rejections***

The Examiner has rejected claims 1-23, 25-42, 110-135 and 137-147 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for foamable pharmaceutical compositions, does not reasonably provide enablement for said compositions devoid of a buffering agent. The Examiner's rejections are respectfully traversed.

Applicant wishes to point out that paragraph [0139] of the instant application describes an exemplary composition according to the teachings of the present invention (referred to as Composition I) that does not contain a weak acid and a conjugate base thereof, thus providing enablement for a composition devoid of a buffering agent.

It is therefore the Applicant's opinion that the specification reasonably provides enablement for the subject matter of independent claim 1, claims 2-23, 25-42, independent claim 110, claims 111-135 and claims 137-147.

Applicant's therefore believes to have overcome the Examiner's rejection in this respect.

### ***35 U.S.C. §112 Second Paragraph Rejections***

The Examiner has rejected claims 22, 25-26, 134 and 137-138 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner's rejections are respectfully traversed. Independent claim 1 (from which claims 25 and 26 depend), claim 22, independent claim 110 (from which claims 137 and 138 depend) and claim 134 have now been amended.

More specifically, in one particular, the Examiner has stated that claims 22 and 134 are vague and indefinite since these claims recite the terms "hexylene glycol

derivative", "sugar derivative" and "starch derivative", whereby it would have been ambiguous what Applicant considered to be derivatives of hexylene glycol, sugar and starch.

Applicant wishes to point out in this respect that the term "derivative" is widely used in the art and that any person skilled in the art knows the meaning of this term.

Moreover, the terms "sugar derivative" and "starch derivative" are common terms encompassing any rearrangement, oxidation, dehydration and the like products of these natural substances.

In fact, there are 350 U.S. Patents that recite "starch derivative" in one or more claims and 110 U.S. Patents that recite "sugar derivative" in one or more claims. Applicant therefore believes that the phrase "sugar derivative" and "starch derivative" are unambiguous to any person skilled in the art.

Although Applicant believes that the term "hexylene glycol derivative" is clear to any skilled artisan, Applicant has chosen, in order to expedite prosecution, to amend claims 22 and 134 so as to no longer recite this term. Further, as argued hereinabove, Applicant believes that the phrases "starch derivative" and "sugar derivative" are unambiguous and hence do not render claims 22 and 134 vague and indefinite.

However, notwithstanding the above, and in order to expedite prosecution, Applicant has chosen to amend claims 22 and 134 so as to no longer recite these terms.

In another particular, the Examiner has stated that claims 25, 26, 137 and 138 are confusing since these claims depend from claim 1, which recites that the composition is devoid of a buffering agent, whereby in claims 25 and 137 weak acids are cited. The Examiner has continued stating that since these weak acids do not dissociate completely, these acids would inherently result in the formation of a buffer.

The Examiner's attention is directed in this respect to Applicant's arguments set forth Re: 112, first rejections.

The Examiner's attention is directed to claims 26 and 138, which recite the limitation: "... wherein said acid is the only source of a respective anion in the composition". This limitation specifically indicates that the composition does not

comprise a buffer system of an acid and its conjugate base, which may exert a buffering effect.

Applicant therefore believes to have overcome the Examiner's rejections in this respect.

### ***35 U.S.C. § 102 Rejection – Nakagawa et al.***

The Examiner has rejected claims 1, 19, 21, 22, 27-29, 110-113 and 131-134 under 35 U.S.C. §102(b) as being anticipated by Nakagawa et al. (U.S. Patent No. 5,352,437). The Examiner's rejections are respectfully traversed. Claims 17, 38, 129 and 145 have been canceled. Claims 1 and 110 have been amended.

Specifically, the Examiner has stated Nakagawa et al. disclose a foamable aerosol preparation for use as the base of cosmetics, quasi drugs, drugs, and so forth, which comprises 0.1-5 w/v % of a surfactant, 0.05-10 w/v % of a lower alcohol and/or a glycol, 3-25 w/v % of water and **60-95 w/v % of n-butane gas**.

Nakagawa et al. teach cracking foam compositions, which are foamable compositions that become foamed when applied to skin and make cracking sound when rubbed by hand. Nakagawa et al. teach that based upon extensive studies it has been found that using n-butane as a gas and a specific amount of a surfactant resulted in a cracking foam preparation (see, for example, column 2, lines 5-16). Nakagawa et al. further teach that the amount of n-butane in the preparation is **60-95 w/v %**, whereby when this amount is less than 60 w/v %, the resulting preparation will be poor in cracking sound. Nakagawa et al. further teach, as the Examiner has stated, that the preparation contains 0.05-10 w/v % of a lower alcohol.

In sharp distinction, the present invention is of quick-breaking foam compositions. As discussed in the instant application, one method of producing quick-breaking foams "*... is by the use of a foamable composition with a relatively high alcohol content. Upon contact with the skin the alcohol in such foams evaporates. Thus the foam relatively quickly collapses into a liquid when disturbed (e.g. by rubbing) or when warmed by body heat driving the active agent through the skin layers to the site of treatment. This allows a user to quickly dispense a desired amount to achieve a quick effect*" (see, paragraph [0009]).

As is further widely described in the instant application, the described and claimed foamable compositions contain relatively high alcohol content, being,

according to preferred embodiments, higher than 40 weight percents (see, for example, paragraphs [0076], [0096]-[0099], [0139], [0140]).

In addition, the compositions of the present invention include a non-CFC propellant in an amount lower than 60 weight percents and even lower than 40 weight percents (see, for example, paragraphs [0090], [0096]-[0099], [0139], [0140]). These teachings are in sharp contrast with the teachings of Nakagawa et al. delineated hereinabove.

Taken together, it is clear that the quick-break foaming composition described and claimed in the instant application substantially differs from the composition taught by Nakagawa et al., both by its composition and the properties of the resulting preparation. While Nakagawa et al. teach that when the amount of n-butane gas (a propellant) is less than 60 w/v %, the resulting preparation will be poor in cracking sound, the present invention teaches compositions in which the amount of a propellant is lower than 60% and is preferably even lower than 40 % and lower than 20%. Other components of the present compositions also differ from those used in Nakagawa et al.

These teachings strongly suggest that the nature of the "quick-break" foamable composition taught by the present invention clearly differs from the "cracking" composition of Nakagawa.

It is therefore argued that the claimed compositions are not anticipated by Nakagawa et al.

Notwithstanding the above and in order to more clearly distinguish the claimed invention from the teachings of Nakagawa et al., Applicant has chosen to amend claims 1 and 110, to include the limitation:

*"..., wherein the concentration of said non-CFC propellant ranges between about 1 weight percentage and about 40 weight percentages of the total weight of the composition."*

Consequently, claims 17 and 38, which included the limitation now added to claim 1, and claims 129 and 145, which included the limitations now added to claim 110, have been canceled.

It is therefore the Applicant's opinion that amended claim 1, claims 19, 21, 22, 27-29, amended claim 110 and claims 111-113 and 131-134 are not anticipated by Nakagawa et al. and are therefore allowable.

***35 U.S.C. § 102 and 103 Rejections – Jones et al.***

The Examiner has rejected claims 1-19, 21-23, 25-40, 110-131, 133-135 and 137-145 under 35 U.S.C. §102(b) as being anticipated by Jones et al. (WO 96/27326). The Examiner has further rejected claims 20, 41, 42, 132, 146 and 147 under 35 U.S.C. §103(a) as being unpatentable over Jones et al. The Examiner's rejections are respectfully traversed. Claims 17, 38, 129 and 145 have been canceled.

Specifically, the Examiner has stated that these rejections are being made based on the instant specification lacking enablement for foamable pharmaceutical compositions devoid of a buffering agent.

In response, Applicant wishes to first point out that in paragraph [0139] of the instant application describes an exemplary composition according to the teachings of the present invention (referred to as Composition I) that does not contain a weak acid and a conjugate base thereof, thus providing enablement for a composition devoid of a buffering agent. In addition, the Examiner's attention is directed to paragraphs [0068] and [0069] of the instant application where it is cited:

*"The present inventors have now surprisingly found that foamable compositions of corticosteroids, which are designed to provide a quick break foam using non-CFC propellants, can be formulated without a buffering agent, while still maintaining the stability of the active ingredients"*

and further:

*"... the foamable compositions of the present invention are exceptionally suitable for use in dispensing pharmaceutically active agents, especially such ingredients that are pH sensitive. This arises from the fact that, for a composition of the present invention, a desired pH is achieved and maintained without the addition of a buffering agent".*

It is therefore clear that since the present invention is of foamable compositions that are advantageously devoid of a buffering agent, whereby Jones et al. teach that a buffering agent is a necessary component in the foamable

compositions taught therein, Jones et al. fail to teach or remotely suggest a foamable composition as described and claimed in the instant application.

It is therefore the Applicant's opinion that claims 1-16, 18, 19, 21-23, 25-37, 39, 40, 110-128, 130, 131, 133-135, and 137-144 are not anticipated by Jones et al. and are therefore allowable.

It is further the Applicant's opinion that claims 20, 41, 42, 132, 146 and 147 are not rendered obvious by Jones et al. and are therefore allowable.

***35 U.S.C. § 103 Rejection – Nakagawa et al.***

The Examiner has rejected claim 30 under 35 U.S.C. §103(a) as being unpatentable over Nakagawa et al. (U.S. Patent No. 5,352,437). The Examiner's rejection is respectfully traversed. Claim 1 (from which claim 30 depends) has been amended.

Specifically, the Examiner has stated that Nakagawa et al. do not anticipate claim 30 because Nakagawa et al. does not disclose a concentration of a corticosteroid between 0.05 and 2 weight percents, and has further stated that it would have been obvious to a person skilled in the art to modify the amount of a corticosteroid in a foamable pharmaceutical composition based on the teachings of Nakagawa et al.

The Examiner's attention is directed in this respect to Applicant's arguments set forth hereinabove regarding the 102 rejection - Nakagawa et al., where the substantial differences between the foamable pharmaceutical composition of the present invention and that taught in Nakagawa et al. are discussed in detail.

Since, as argued hereinabove, Applicant believes that Nakagawa et al. do not anticipate the compositions described and claimed in the instant application, it is further believed that the teachings of Nakagawa et al. do not render the claimed compositions obvious, regardless of the concentration of the corticosteroid therein.

It is therefore the Applicant's opinion that claim 30 is not rendered obvious by Nakagawa et al. and is therefore allowable.

***35 U.S.C. § 103 Rejection – Nakagawa et al. in view of Quigley et al.***

The Examiner has rejected claims 2-18, 20, 25, 26, 31, 34-47, 39-42, 114-128, 132, 135, 137-139 and 141-144 under 35 U.S.C. §103(a) as being unpatentable over Nakagawa et al. (U.S. Patent No. 5,352,437), as applied to claim 30 above, and

further in view of Quigley et al. (U.S. Patent No. 6,075,056). The Examiner's rejections are respectfully traversed. Claims 17, 38, 129 and 145 have been canceled. Independent claims 1 and 110 have been amended.

The Examiner has stated that while Nakagawa et al. lacks teachings of a carrier comprising at least one fatty alcohol, at least one hydrocarbon alcohol and at least one surface-active agent and water, Quigley et al. teach topical compositions comprising an anti-fungal agent and an anti-inflammatory steroid, which may further comprise excipients that include some of the components mentioned as comprising the carrier described and claimed in the instant application. The Examiner has further stated that Quigley et al. teach a composition which may be provided in a variety of forms, including foams. The Examiner has concluded that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Nakagawa et al. and Quigley et al.

The substantial differences between the claimed invention and the teachings of Nakagawa et al. are set forth hereinabove.

Quigley et al. teach topical compositions which may include a variety of excipients, some are encompassed by optional components that are used for forming the "*carrier configured to generate a quick-break foam*", described and claimed in the instant application. However, while Quigley et al. mention in passing foams as an optional form of the compositions taught therein, Quigley et al. are completely silent with respect to the propellants used for such compositions and with respect to the foaming nature of such compositions. In particular, Quigley et al. fail to teach or remotely suggest quick-breaking foam compositions.

In sharp distinction, the present invention is of foamable compositions designed to form a quick-break foam. The advantageous features of such compositions are mentioned throughout the instant application (see, for example, paragraph [0067]).

In view of the substantial differences between the claimed invention and the teachings of Nakagawa et al. and further in view of the lack of teachings of a foamable composition, particularly a quick-breaking foamable composition, in Quigley et al., it is clear that a person having an ordinary skill in the art would not have been motivated to combine the teachings of Nakagawa et al. and Quigley et al., to thereby obtain the compositions described and claimed in the instant application.



It is therefore the Applicant's opinion that claims 2-16, 18, 20, 25, 26, 31, 34-47, 39-42, 114-128, 132, 135, 137-139 and 141-144 are not rendered obvious by Nakagawa et al. in view of Quigley et al. and are therefore allowable.

### ***Double Patenting***

The Examiner has stated that should claim 32 is found allowable, claim 33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof, in view of only a slight difference in wording.

Applicant respectfully traverses the Examiner's notion in this respect.

Applicant wishes to clarify in this respect that claim 32 recites a pharmaceutical foamable composition which is packaged in a packaging material and is identified in print, in or on the packaging material, for use for a need that relates to a condition, whereby claim 33 recites preferred conditions that such a need relates to. Applicant therefore believes that claim 33 is not a substantial duplicate of claim 32.

However, in order to more clearly define the subject matter of claim 32, claim 32 has been amended to recite:

*"32. The foamable pharmaceutical composition of claim 1, .... wherein said condition is selected from the group consisting of acute inflammatory diseases, allergic contact dermatitis, eczema, atopic eczema, asteatotic eczema, discoid eczema, infantile eczema and napkin dermatitis, psoriasis – plaque, seborrheic dermatitis, atopic dermatitis, dermatitis herpetiformis, neurodermatitis, lichen simplex chronicus, lichen planus, subacute cutaneous lupus erythematosus, papular urticaria, palmoplantar psoriasis, discoid lupus erythematosus, chronic hypertrophic lichen planus, granuloma annulare and keloid scars."*

Consequently, claim 33, which included the limitations now added to amended claim 32, has been canceled.

### ***Other matter***

The Examiner has noted that the word "isobutane" was misspelled as "isobutene" in claims 41 and 146. Claims 41 and 146 have been corrected so as to appropriately spell the word "isobutane".

*Examination of generic claims*

In view of the amendments made to the claims and the arguments recited herein it is believed that the claims are allowable with respect to the elected invention.

Examination of claims 1-16, 18-37, 38-42, 110-128, 130-144 and 145-147 in their generic context and with respect to all the species recited therein is therefore respectfully requested.

In view of the above amendments and remarks it is respectfully submitted that amended claim 1, claims 2-16, 18-21, amended claim 22, claims 23-31, amended claim 32, claims 33-37, 39, and 40, amended claim 41, claim 42, amended claim 110, claims 111-128, 130-133, amended claim 134, claims 135-144, amended claim 146 and claim 147 are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,



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**Encl.:**

Petition for Extension of Time (3 Months)